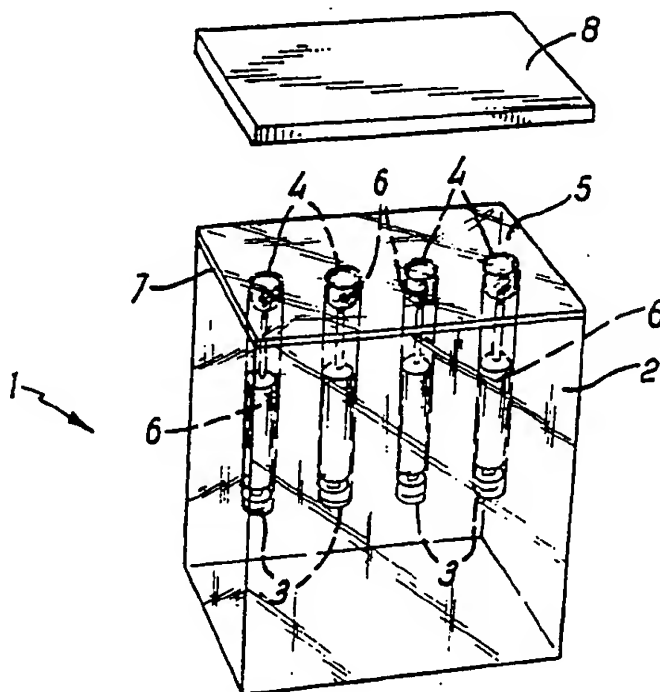




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(54) Title: STERILE PACKAGING



(57) Abstract

Articles such as dentists' drill bits (6), or dental pins (26), are sealed under sterile conditions in receptacles (3, 18). The articles (6, 26) are removed from the receptacles (3, 18) through entries (4, 19) by braking the seal. The seal may be provided by a skin (7) bonded over the entries (4, 19). An implement (9, 29) may be used for removing an article. In one embodiment multiple receptacles (18) are provided around a circular structure (12) and there is a lid (21) which can be rotated to expose the sealed receptacles one at a time.

# + DESIGNATIONS OF "SU"

It is under examination in which parts of the former Soviet Union the designation of the Soviet Union has effect.

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## STERILE PACKAGING

### TECHNICAL FIELD

This invention relates to sterile packaging.

### BACKGROUND ART

Bits for dentists' drills are commonly supplied in a compartmentalised container with a movable cover. To use a bit, the cover is moved to expose one compartment. The bit in the compartment is removed, sterilised and attached to the drill. After use, the bit can be re-sterilised and is often stored in a hole in a block-shaped stand until it is again required for use.

With this known procedure there is the inconvenience of having to sterilise newly supplied bits and also there is the problem that the re-sterilised bits may become contaminated whilst they are stored in the stand awaiting re-use.

### DISCLOSURE OF THE INVENTION

An object of the present invention is to provide sterile packaging with which articles can be stored conveniently and so as to be readily accessible under sterile conditions.

According to one aspect of the invention therefore there is provided a sterile packaging system comprising a receptacle with an entry thereto, an article sealed under sterile conditions in the receptacle, and an implement insertable through said entry, said implement being

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operable to disrupt the seal at said entry and to grip the article in the receptacle whereby the article can be removed from the sealed receptacle with the implement.

With this arrangement, the article is stored under sterile conditions within the receptacle and can be readily removed when desired by use of the implement. By use of a suitable sterile implement, it can be possible to remove the article without introducing contamination thereto. The implement may releasably grip the article and may be used to transfer the article to a position of use, the implement then being removed from the article. Alternatively, the arrangement may be such that the article is used with the implement attached thereto whereby the implement may grip the article releasably or permanently.

The packaging system of the invention may be used in the context of a bit for a dentists' drill, whereby the bit comprises the said article. In this context the implement may be part of the dentists' drill which is inserted through the entry into the receptacle, or the implement may be a separate transfer device which is used to pick up the bit and transfer it to the drill.

The article may be a dental pin having a threaded part at one end to be drilled into a tooth and a mounting part at its opposite end to be connected to a dentists' drill. In particular the pin may be of the kind, as described in PCT/GB90/01130 (WO91/01693), having a cap arranged to fit over a drill bit in a dentists' drill bit

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and in this case the mounting part may face the entry of the receptacle and the drill bit may be used as the implement.

The invention may be used for any suitable kind of articles used for any suitable purpose including, but not restricted to, tools, instruments, devices and materials for use in dentistry, medicine, surgery, food preparation etc. Dental, medical and surgical tools and instruments such as drill bits and pins mentioned above, scalpels, blades etc. may be particularly suitable but the invention is not restricted to this.

With regard to the sealing of the entry of the receptacle, this may be achieved in any suitable manner. It may be achieved with a rupturable skin, and/or a displaceable cover or lid, or even the gripping implement itself acting e.g. as a sealing plug. Most preferably the entry is sealed by means of a rupturable skin. Thus, and in accordance with a second aspect of the invention there is provided a sterile packaging system comprising a receptacle with an entry thereto, and an article sealed under sterile conditions in the receptacle, wherein the entry is sealed with a rupturable skin whereby the article can be removed through the entry after rupturing of the skin.

Any or all of the features of the system of the first aspect of the invention may be applied to the system of the second aspect of the invention.

With regard to the rupturable skin this may be of any

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suitable material and may be fixed in position in any suitable manner. In a preferred embodiment the skin is formed from a plastics film, such as polyethylene, and fixing is achieved by adhesive bonding around the periphery of the entry. In addition to the rupturable skin a removable lid may be provided over the entry.

With both the first and second aspects of the invention there may be multiple receptacles defined for example by multiple side by side compartments formed in a common body structure, and there may be a supplementary receptacle for the implement. In this case there may be a displaceable lid which can be moved to expose the sealed entries e.g. one at a time. In one arrangement especially where the articles are bits for dentists' drills, or pins to be drilled into tooth stumps, the compartments may be arranged side by side around a circular structure with a rotatable lid movable to expose successive entries.

Sterilisation of the packaged articles may be achieved in any suitable manner. Since the articles are sealed within the receptacles sterilisation can be achieved in situ using e.g. gamma radiation or ethylene oxide.

The arrangement with the first and/or second aspects of the invention may be such that the receptacle is re-sealable after removal of the article. In this way, the article (or a different article) can be re-inserted in the receptacle, sealed and sterilised ready for subsequent

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use.

In accordance with a further aspect of the invention there is provided a method of dispensing an article which is packaged in a receptacle with an entry thereto, said article being sealed under sterile conditions in the receptacle, characterised in that an implement is inserted through the entry to disrupt the seal at said entry and to grip the article in the receptacle, and the article is then removed from the receptacle with the implement.

In accordance with a yet further aspect of the invention there is provided a method of dispensing an article which is packaged in a receptacle with an entry thereto, said article being sealed under sterile conditions in the receptacle, characterised in that the article is removed through the entry after rupturing a skin which seals said entry.

In a preferred embodiment there is provided a method as described above further including the steps of inserting an article into the receptacle from which the first said article has been removed, and re-sealing the receptacle and re-sterilising the contents thereof.

#### BRIEF DESCRIPTION OF DRAWINGS

The invention will now be described further by way of example only and with reference to the accompanying drawings in which:-

Fig. 1 is a schematic, exploded perspective view of an arrangement of packaged articles in accordance with one embodiment of the

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invention;

Fig. 2 is a diagrammatic sectional view showing removal of one article with a gripping implement;

Fig. 3 is a schematic, exploded perspective view of an arrangement of packaged articles in accordance with an alternative embodiment of the invention; and

Fig. 4 is a diagrammatic view.

#### BEST MODES FOR CARRYING OUT THE INVENTION

Referring now to Figs. 1 & 2, a storage device 1 for bits for a dentists' drill comprises a block 2 of clear, rigid plastics material with a row of parallel side-by-side blind bores 3 defining cylindrical receptacles with entry openings 4 at a top face 5 of the block.

The compartments 3 contain respective bits 6. The top face 5 of the block 2 is flat and is covered with a film of polyethylene 7. The film 7 is held in position by means of a thin layer of adhesive which extends in the regions around the peripheries of the entries 4. The film 7 therefore seals the entries 4.

The film 7 is covered with a lid 8 which snap fits on to the top of the block 2 to protect the film 7.

The sealed compartments 3 containing the bits 6, and the bits 6 within the compartments 3, are sterile. This may be achieved for example by use of gamma radiation after sealing.



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A bit 6 can be removed when desired by rupturing the film 7 using an implement 9 as shown in Fig. 2. The implement 9 is pushed through the film 7 into the entry 4 of one compartment 3. To do this, the lid 8 may first be removed. Alternatively, the lid 8 may have open (or openable) through holes through which the implement 9 can be pushed without removing the lid 8.

The implement 9 which is a springy tubular plastics device is moved into engagement with the cutting head 10 of the bit 6 in the compartment 3. The head 10 is gripped and the bit 6 can be pulled out of the compartment 3. The shank 11 of the bit 6 can then be inserted into the chuck of the drill and the implement 9 can then be pulled off the bit 6.

With this arrangement, the head 10 of the bit 6 is touched only by the end of the implement 9 so sterile conditions can be maintained. The implement 9 can be initially supplied in sterile condition in a separate openable compartment or container (not shown). After use the implement 9 can be re-sterilised or may be discarded in favour of a new sterilised implement.

Between use drill bits 6 can be stored in a block-type stand in conventional manner. After use, bits 6 can be re-sterilised and re-sealed in the sterile compartments 3 of the storage device 1 (or a fresh storage device) using fresh, sterile film 7. The lid 8 may be re-sterilised or may be discarded and replaced with a new lid.

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Fig. 3 shows a storage device comprising a circular plastics body 12 having a cylindrical side wall 13 formed integrally with a disc-shaped bottom end wall 14. In the centre of the end wall 14 there is an upstanding integral tubular pivot member 15.

The cylindrical side wall 13 is shaped to define multiple integral side-by-side cylindrical elements 16. One element 16 is cut away to define a slot 17. A further element 16 adjacent the cut away element 17 is solid. All other elements 16 have blind bores 18 defining cylindrical compartments with entries 19 at the top face 20 of the side wall 13.

All of these compartments 18 contain dental pins 26 (see Fig. 4) which comprise threaded metal pins 27 intended to be drilled into a tooth stump to give support for a synthetic crown. The pins have integral plastics mounting caps 28 which are intended to fit over the end of a drill bit 29 and have weakened waist portions 30 for shearing purposes, as described in PCT/GB90/01130 (WO 91/01693).

The compartments 18 are sealed by means of a film (not shown) of adhesive-backed polyethylene applied to the top face 20 of the wall 13 over the entries 19.

The sealed entries 19 are covered with a rotatable lid 21. The lid 21 comprises a generally disc-shaped recessed body having a central tubular part 22 which snap fits over the upstanding tubular pivot member 15. The periphery 23 of the lid rests on and covers the sealed

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entries 19. Underneath this periphery 23 there is a springy ratchet pawl 24 which is pressed against the inner surface of the upstanding wall 13. The pawl 24 engages in ratchet manner the recesses between the cylindrical elements 16.

The lid periphery 23 has a cut away portion 25 of similar dimensions to the top of one of the elements 16. Underneath the lid there is a radially extending compartment (not shown) which has an open end beneath the cut away portion 25. This compartment contains a drill bit 29.

The storage device is supplied with the cut away portion 25 level with the solid element 16a. The entries 19 of the compartments 18 in the elements 16 are thereby all covered and the open end of the radial compartment is covered. All compartments and the contents thereof are sterilised e.g. using gamma radiation.

In use, the lid 21 is clicked to a position at which the cut away portion 25 is level with the slot 17. The drill bit 29 is removed, sterilised further if necessary, and attached to the drill in normal manner.

The lid 21 is then clicked to a position at which the cut away portion 25 overlies the top of the first compartmentalised element 16. This exposes the film-covered entry 19. The bit 29 is pushed through the film to rupture this and the bit is engaged with the pin 26 in the compartment 18 (as shown in Fig. 4). The pin 26 is thereby removed ready for use without requiring any

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contaminating contact.

With the embodiments described above articles can be stored in sterile conditions in a convenient manner and such that there is ready access to the articles.

It is of course to be understood that the invention is not intended to be restricted to the details of the embodiments which are described by way of example only.

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Claims

1. A sterile packaging system comprising a receptacle (3) with an entry (4) thereto, and an article (6) sealed under sterile conditions in the receptacle (3), characterised by the provision of an implement (9) insertable through said entry (4), said implement (9) being operable to disrupt the seal (7) at said entry (4) and to grip the article (6) in the receptacle (3) whereby the article (6) can be removed from the sealed receptacle (3) with the implement (9).
2. A sterile packaging system comprising a receptacle (3) with an entry (4) thereto, and an article (6) sealed under sterile condition in the receptacle (3), characterised in that the entry (4) is sealed with a rupturable skin (7) whereby the article (6) can be removed through the entry (4) after rupturing of the skin (7).
3. A system according to claim 2 characterised by the provision of an implement (9) insertable through said entry (4), said implement (9) being operable to rupture the skin (7) at said entry (4) and to grip the article (6) in the receptacle (3) whereby the article (6) can be removed from the sealed receptacle (3) with the implement (9).
4. A system according to any one of claims 1 to 3 characterised by the provision of a displaceable lid (8) over said entry (4).
5. A system according to any one of claims 1 to 4 characterised by the provision of multiple said

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receptacles (3) in a common body (2) each with a respective said article (6) sealed under sterile condition therewithin.

6. A system according to claim 4 and claim 5 characterised in that the lid (21) is displaceable through a plurality of positions to expose a respective said entry (19) at each said position.

7. A system according to claim 6 characterised in that the receptacles (18) are arranged side by side around a circle and the lid (21) has an opening (25) therein and is rotatable about the centre of the circle to bring the opening (25) into alignment successively with the entries (19) of the receptacles (18) at the said positions of the lid (21).

8. A system according to claim 7 characterised by the provision of a ratchet and pawl arrangement (24) between the lid (21) and the body (12) to effect alignment of the opening (25) and the entries (19) at the said positions of the lid (21).

9. A system according to any one of claims 1 to 8 characterised in that the (or each) article (6) comprises a tool or instrument for dental, medical or surgical use.

10. A system according to claim 9 when dependant on claim 1 characterised in that the article (6) comprises a dentists' drill bit having a cutting head (10) at one end and a mounting shank (11) at its opposite end, the bit being located in the receptacle (3) with its cutting head (10) facing the entry (4).

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11. A system according to claim 10 characterised in that the implement (9) comprises a tubular device which is releasably engageable with the cutting head (10) of the bit.

12. A system according to claim 9 characterised in that the article comprises a dental pin (26) having a threaded part (27) at one end to be drilled into a tooth and a mounting part (28) at its opposite end to be connected to a dentists' drill.

13. A system according to claim 12 when dependent on claim 1 characterised in that the mounting part (28) comprises a cap arranged to fit over a drill bit (29) in a dentists' drill, said mounting part (28) facing the entry (19) of the receptacle (18) and the implement comprising said drill bit (29).

14. A system according to claim 5 when dependent on claim 1, or according to any claim dependent thereon characterised in that said body (12) has a supplementary receptacle (17) containing said implement (29).

15. A method of dispensing an article (6) which is packaged in a receptacle (3) with an entry (4) thereto, said article (6) being sealed under sterile conditions in the receptacle, characterised in that an implement (9) is inserted through the entry (4) to disrupt the seal (7) at said entry (4) and to grip the article (6) in the receptacle (3), and the article (6) is then removed from the receptacle (3) with the implement (9).

16. A method of dispensing an article (6) which is

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packaged in a receptacle (3) with an entry (4) thereto, said article (6) being sealed under sterile conditions in the receptacle (3), characterised in that the article (6) is removed through the entry (4) after rupturing a skin (7) which seals said entry (4).

17. A method according to claim 15 when using the system of any claim dependent on claim 1.

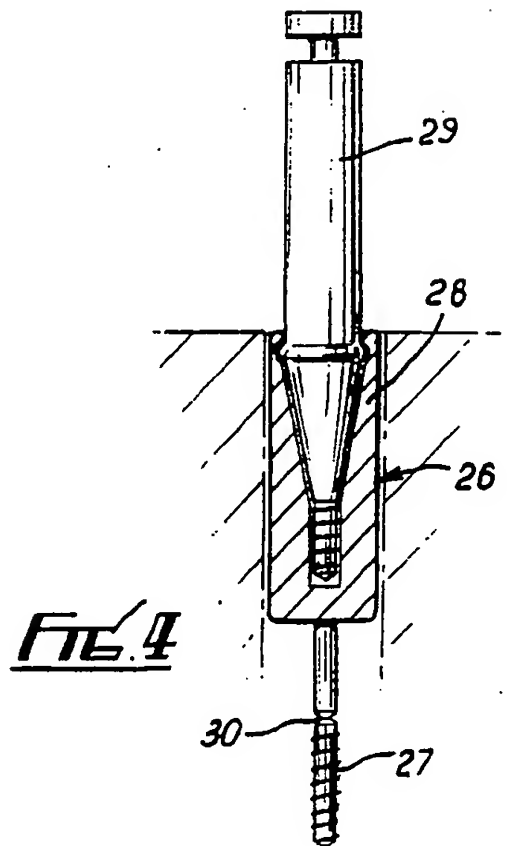
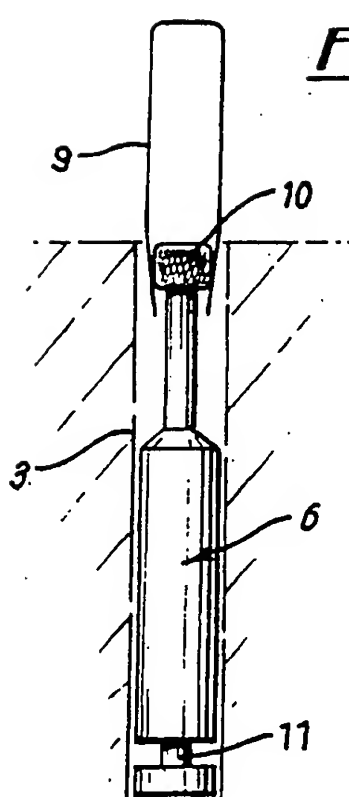
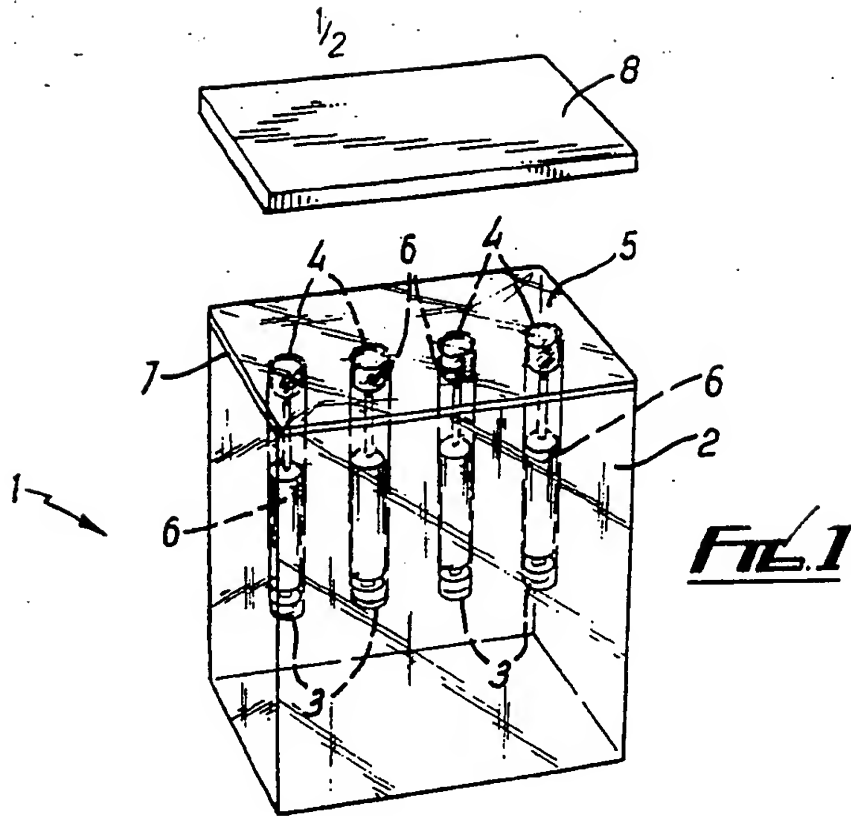
18. A method according to claim 16 when using the system of any claim dependent on claim 2.

19. A method according to any one of claims 15 and 18 further including the steps of inserting an article (6) into the receptacle (3) from which the first said article (6) has been removed, and re-sealing the receptacle (3) and re-sterilising the contents thereof.

20. A system according to claim 1 or claim 2 substantially as hereinbefore described with reference to and as illustrated in the accompanying drawings.

21. A method according to claim 15 or claim 16 substantially as hereinbefore described with reference to the accompanying drawings.





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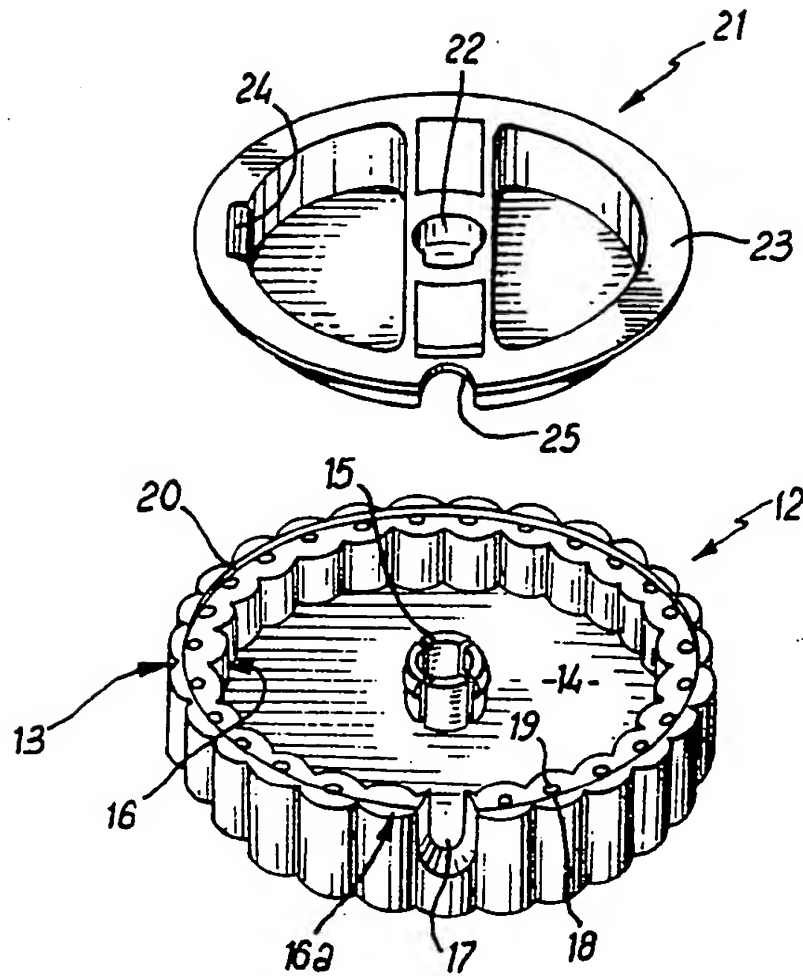


FIG. 3

## INTERNATIONAL SEARCH REPORT

PCT/GB 91/01137

International Application No

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all)<sup>6</sup>

According to International Patent Classification (IPC) or to both National Classification and IPC:

Int.Cl. 5 A61C19/02

## II. FIELDS SEARCHED

Minimum Documentation Searched<sup>7</sup>

Classification System

Classification Symbols

Int.Cl. 5

A61C ; A61B ; A61L

Documentation Searched other than Minimum Documentation  
to the Extent that such Documents are Included in the Fields Searched<sup>8</sup>III. DOCUMENTS CONSIDERED TO BE RELEVANT<sup>9</sup>

Category <sup>9</sup>	Citation of Document, <sup>11</sup> with indication, where appropriate, of the relevant passages <sup>12</sup>	Relevant to Claim No. <sup>13</sup>
X	US,A,4 106 620 (BRIMMER ET AL.) August 15, 1978 see column 1, line 65 - column 2, line 35 see column 4, line 15 - line 23; figure 1	1-3,5,9, 14-21
Y	---	10-12
X	US,A,4 746 016 (POLLAK ET AL.) May 24, 1988 see column 4, line 64 - column 5, line 5 see column 7, line 22 - line 31; figures 1-3	1-5,9, 14-21
Y	---	10-12
Y	DE,B,1 038 714 (WALSER) September 11, 1958 see column 3, line 55 - column 4, line 10; figures 1,2,4,6,8	10-12
A	---	6
	US,A,2 835 377 (MAY ET AL.) May 20, 1958 see column 1, line 15 - line 38; figure 1 ---	
	-/--	

<sup>9</sup> Special categories of cited documents: <sup>10</sup><sup>"A"</sup> document defining the general state of the art which is not considered to be of particular relevance<sup>"E"</sup> earlier document but published on or after the international filing date<sup>"L"</sup> document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)<sup>"O"</sup> document referring to an oral disclosure, use, exhibition or other means<sup>"P"</sup> document published prior to the international filing date but later than the priority date claimed<sup>"T"</sup> later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention<sup>"X"</sup> document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step<sup>"Y"</sup> document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.<sup>"&"</sup> document member of the same patent family

## IV. CERTIFICATION

Date of the Actual Completion of the International Search

04 OCTOBER 1991

Date of Mailing of this International Search Report

25. 11. 91

International Searching Authority

EUROPEAN PATENT OFFICE

Signature of Authorized Officer

GIMENEZ BURGOS R.

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category °	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	US,A,2 557 420 (ELLIOT) June 19, 1951 see column 2, line 22 - line 37 see column 3, line 60 - line 73 see column 4, line 53 - line 63; figure 1 ---	1

# ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.

GB 9101137  
SA 49446

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.  
The members are as contained in the European Patent Office EDP file on  
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04/10/91

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-4106620	15-08-78	CA-A- 1071393 DE-A- 2828894 JP-A- 54054486	12-02-80 12-04-79 28-04-79
US-A-4746016	24-05-88	EP-A- 0343311	29-11-89
DE-B-1038714		None	
US-A-2835377		None	
US-A-2557420		None	

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